UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DAVID HACKEL, Individually, and On Behalf of All Others Similarly Situated, Plaintiff, v. AVEO PHARMACEUTICALS, INC., MICHAEL BAILEY, MATTHEW DALLAS, KEITH S. EHRLICH, and MICHAEL NEEDLE, Defendants.	Case No. 1:19-cv-10783-ADB CLASS ACTION Hon. Allison D. Burroughs **AMENDED COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** JURY TRIAL DEMANDED

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Lead Plaintiff Andrej Hornak ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding AVEO Pharmaceuticals, Inc. ("AVEO" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired AVEO securities between May 4, 2017 through January 31, 2019, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. AVEO is a biopharmaceutical company incorporated in 2001. At all times relevant hereto, AVEO's lead candidate drug was tivozanib (registered under the trademarked name FOTIVDA), which is an oral, once-daily medication for treating renal cell carcinoma ("RCC"). AVEO's earnings reports during the Class Period noted that the company's ability to survive was "substantially dependent on the success of tivozanib."

3. In December 2008 and May 2009, AVEO met with the FDA regarding the design of a Phase 3 trial assessing tivozanib as a first-line treatment for renal cell cancer. The study, known as TIVO-1, tested tivozanib against an already approved but outdated drug, sorafenib.

4. TIVO-1 was the only pivotal clinical trial that AVEO conducted to support an NDA for tivozanib. Defendants did not conduct TIVO-1 in the manner discussed and agreed upon with the FDA. Instead, they took three shortcuts which helped speed enrollment, make the study less expensive, and boost results, but compromised its scientific integrity. AVEO did not inform investors of these shortcuts.

5. AVEO also did not inform investors that on May 11, 2012, at a formal meeting held with the U.S. Food & Drug Administration ("FDA") over the new drug application ("NDA") required to be submitted so that tivozanib could be marketed in the United States, the FDA raised concerns about the data they were seeing from TIVO-1. At that meeting, the FDA: (i) recommended that AVEO conduct a whole new well-controlled pivotal clinical trial in an appropriate patient population; (ii) expressed serious concern about the higher death rate in the tivozanib arm of the TIVO-1 study; (iii) criticized the Company's decision to modify TIVO-1 to include a one-way crossover; (iv) questioned whether AVEO should file an NDA at all in light of the compromised TIVO-1 study; and (v) warned that the defective design of the TIVO-1 study made it difficult to tell whether tivozanib was "toxic."

6. AVEO scrambled to design a second trial ("TIVO-2"), but the FDA expressed significant concerns regarding the design for TIVO-2. AVEO scrapped the plan for TIVO-2 and decided to submit the NDA without having run a second trial.

7. While on August 2, 2012, AVEO chose to admit to the public that the FDA had concerns regarding the overall survival ("OS") in TIVO-1, the company failed to disclose that

the agency had recommended a second adequately-powered trial in a comparable population, that the agency questioned whether AVEO should even file an NDA, or that the agency had expressly warned that adverse overall survival trends could affect the drug's approval possibilities.

8. In June 2013, tivozanib was deemed insufficient for approval by the FDA, over reported concerns regarding the negative trend in OS in TIVO-1. In other words, as the FDA expressed concerns about in May 2012, patients randomized to the tivozanib arm of TIVO-1 were dying at a faster rate than those in the control arm.

9. AVEO's stock plummeted as a result of this rejection. Importantly, as AVEO had misled investors by not disclosing pertinent details about TIVO-1 and the company's interactions with the FDA, on March 29, 2016, the Securities and Exchange Commission ("SEC") brought fraud charges against AVEO and three officers who have since left the company: CEO Tuan Ha-Ngoc, chief financial officer David Johnston, and chief medical officer William Slichenmyer. AVEO agreed to pay a $4 million penalty to settle the SEC's charges against it without admitting or denying the allegations in the complaint. Ha-Ngoc and Slichenmyer later settled. Johnson went to trial and a jury found he defrauded investors. Multiple civil lawsuits were also filed.

10. On May 26, 2016, AVEO announced the dosing of its first patient in the "TIVO-3 trial," the Company's Phase 3 randomized, controlled, multi-center, open-label study to compare tivozanib to sorafenib in 351 subjects with highly refractory advanced or metastatic. According to AVEO, the TIVO-3 trial was designed to address the overall survival concerns from the TIVO-1 trial presented in June 2013.

11. In the following couple of years, AVEO hid that the amount of progression free survival events was too low to perform a topline data analysis on the TIVO-3 data when AVEO had announced it would perform that data analysis.

12. After months of delays, on October 1, 2018 ("October 1 Press Release"), AVEO finally announced it had initiated topline analysis of TIVO-3, but the study would not be powered as expected. Instead of waiting until 255 progression free survival events, the company was performing its analysis at 242 events, reducing the power of the study, despite the fact that Defendant Bailey had spoken previously about how important robustly powering the study was to the drug's chances of success.

13. On November 5, 2018, AVEO issued a press release announcing that tivozanib had successfully "met its primary endpoint of demonstrating a statistically significant benefit in progression-free survival (PFS)" through the TIVO-3 trial (the "November 5 Press Release").

14. The November 5 Press Release stated that the data on OS, which was a secondary endpoint of TIVO-3, was not mature at the time of the final PFS analysis, with only 46% of potential OS events having been reported. It further stated that at the time of the preliminary OS analysis, no statistically significant difference in OS was observed. However, in reality, while the preliminary OS differences between tivozanib and the control arm were not statistically significant, they were there, just as they had been there in TIVO-1. The hazard ratio ("HR")[1] was announced as 1.06 (though AVEO would later disclose that this figure was incorrect).

15. In a conference call that same day, Defendant Needle downplayed the negative OS results, stressing how the results were preliminary. He even presented a slide about how the preliminary OS results for a Phase 3 study for axtinib (trademark name Inlyta), another RCC

[1] The hazard ratio is the relative risk of an event happening at a given time. For example, a hazard ratio of two in a clinical trial means that two times the number of events are seen in the treatment group at any point in time.

drug that was later approved by the FDA, also were higher in the axtinib arm. What he neglected to provide was context: unlike tivozanib, axtinib had not previously been questioned by the FDA for an increased death rate among study participants receiving the drug.

16. According to the November 5 Press Release, AVEO planned to submit a NDA to the FDA in approximately six months based on results from the TIVO-3 trial, together with the previously completed Phase 3 TIVO-1 trial of tivozanib in the first line treatment of RCC. Defendant Needle reiterated this during the related conference call.

17. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) tivozanib had insufficient survival data to meet FDA approval following its initial 2013 rejection by the FDA; (ii) the survival data Defendants presented to the public did not include all OS events; and (iii) this lack of sufficient survival data would put tivozanib at greater risk of delayed FDA approval.

18. On January 31, 2019, AVEO announced ("January 31 Press Release") it had accepted the FDA's recommendation to not submit a NDA for tivozanib with the preliminary OS data the company currently had. According to AVEO: "The FDA indicated that these preliminary OS results do not allay their concerns about the potential detriment in OS outlined in the complete response letter dated June 6, 2013. The Company now plans to make a NDA filing decision following the availability of more mature OS results."

19. The January 31 Press Release also stated that AVEO had somehow "identified the survival status of a group of patients that were previously lost to follow up." This group made the OS stats for the trial even worse, increasing the HR from 1.06 to 1.12. In other words,

AVEO claimed they found data—without explaining why it was lost—and that data just happened to hurt their overly rosy narrative.

20. On this news, AVEO's stock price dropped $1.07 per share, or over 60%, to close at $0.70 per share on January 31, 2019.

21. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

22. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

23. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and Section 27 of the Exchange Act.

24. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). AVEO maintains its principal place of business in this District and many of the acts and practices complained of occurred in substantial part herein.

25. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

26. Plaintiff Hornak acquired AVEO purchased AVEO common stock during the Class Period as set forth in the certification previously filed with this Court and was damaged as the result of Defendants' wrongdoing as alleged in this complaint.

27. Defendant AVEO is a Delaware corporation with its principal executive offices located at One Broadway, 14th Floor, Cambridge, Massachusetts 02142. AVEO's shares trade in an efficient market on the NASDAQ Global Stock Market ("NASDAQ") under the ticker symbol "AVEO".

28. Defendant Michael Bailey ("Bailey") has served as the Chief Executive Officer ("CEO") and President of AVEO at all relevant times since January 7, 2015, and served as the Company's Secretary. Bailey served as the Principal Financial Officer of AVEO until April 2015.

29. Defendant Matthew Dallas ("Dallas") has served as the Chief Financial Officer ("CFO") of AVEO at all relevant times since June 1, 2017.

30. Defendant Keith S. Ehrlich ("Ehrlich") served as the CFO of AVEO at all relevant times from April 22, 2015 to July 1, 2017.

31. Defendant Michael Needle ("Needle") has served as the Chief Medical Officer ("CMO") at all relevant times since January 9, 2015.

32. The Defendants referenced above in ¶¶ 28-31 are sometimes referred to herein collectively as the "Individual Defendants."

33. The Individual Defendants possessed the power and authority to control the contents of AVEO' SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of the Company's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with the Company, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been

disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

The FDA New Drug Approval Process

34. In the United States, pharmaceutical development and marketing is regulated by the FDA, an agency of the U.S. Department of Health and Human Services. The modern regulatory regime was enacted in 1962, after Thalidomide, a sleeping pill, caused birth defects in thousands of babies. In reaction to this tragedy, Congress passed the Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act (the "FDCA") requiring that any company that wanted to market a pharmaceutical product in the United States (in industry parlance, a "sponsor") had to obtain prior approval from the FDA, and that the approval had to be based upon substantial scientific evidence demonstrating that the product was safe and effective for its intended use in humans.

35. The FDCA, as amended, requires the Commissioner of the FDA to refuse any drug application if:

1) "he has insufficient information to determine whether such drug is safe for use under such conditions;" or
2) "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended," or
3) "suggested in the proposed labeling thereof."

21 U.S.C. § 355(d)(4)-(5).

36. The FDA is only permitted to consider clinical evidence to be "substantial," and thus satisfy the FDCA, if it: consist[s] of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. 21 U.S.C. § 355(d). Well-controlled clinical investigations measure the subject drug against a control group, which is provided either a placebo or another already approved drug for comparison. The sponsor, not the FDA, is responsible for determining the design of clinical trials and the protocols for each trial.

37. Sponsors are also responsible for enrolling patients in clinical trials. Regardless of where patients are enrolled, a sponsor must ensure that the trial is conducted according to protocol, and must demonstrate benefit to the patient population for which approval is sought. A sponsor generally conducts clinical trials in three phases. Phase 3 studies are the final study hurdle for a drug. Phase 3 studies are expanded studies "performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects." 21 C.F.R. § 312.21. Those studies which a sponsor uses to support approval in an NDA are known as "pivotal" clinical trials. Both TIVO-1 and TIVO-3 are Phase 3 trials.

38. The sponsor selects which of its officers, employees and consultants will attend meetings with the FDA. Pre-NDA meetings and End-of-Phase 2 meetings are formal meetings

that occur pursuant to FDA procedures and regulations. Briefing books or synopses of data are provided to the FDA reviewers prior to these meetings.

39. When a sponsor believes it has conducted sufficient well-controlled clinical trials, and believes that those trials demonstrate substantial evidence of efficacy and safety consistent with the FDCA, the sponsor may prepare and file an NDA with the FDA seeking approval to the market the subject drug in a specific dose for the treatment of a specific condition or "indication."

40. An NDA accepted for filing is reviewed for substance by the FDA's Center for Drug Evaluation & Research ("CDER"). Prior to the PDUFA date, CDER may (or may not) convene an advisory committee to provide it with technical advice, enhance its decision-making process, and provide a forum for public discussion of controversial issues.

41. Critically, an advisory committee is the only forum in which the public can legally be advised by the FDA of the FDA's position and the FDA's interactions with the sponsor regarding the drug candidate. Except in advisory committee briefing documents and during the advisory committee hearing, FDA secrecy regulations strictly prohibit the agency from disclosing information regarding pending NDAs. As a result, without an advisory committee, the FDA may not publicly refute a sponsor's misrepresentations regarding clinical trials, protocols, or the sponsor's interactions with the FDA, no matter how false or misleading those statements may be. *See* 21 C.F.R. § 314.430.

42. Therefore, without an advisory committee meeting on TIVO-3, investors can only rely on AVEO's incomplete disclosures.

Endpoints in clinical cancer studies

43. Safety and efficacy take on particular importance for cancer drugs like tivozanib, because they are generally toxic and can be lethal to patients even if effective in stopping the

progress of a disease. Accordingly, trials for drugs intended to treat cancer generally measure both *overall survival*, which measures the length of time from the start of treatment in which the patient remains alive, and *progression-free survival*, the length of time after the start of treatment in which the patient remains alive and the disease, as assessed by study researchers, has not worsened.[2] The difference between *overall survival* and *progression-free survival* is summarized in this chart:

	Overall Survival	**Progression-Free Survival**
Permitted by FDA to serve as primary endpoint of Phase 3 clinical trial for renal cell carcinoma?	Yes	Yes, but overall survival is routinely also considered by the FDA in such cases
Method of measurement	Patient death	Mostly radiologic scans of tumor size, and to a much lesser extent, patient death
Cost of sufficiently powering trial to assess statistical significance)	Very expensive	Less expensive
Time required to measure	Significantly more, because measurement cannot be made until patient dies	Much less, because the vast majority of measurement can be accomplished by radiologic scan
Confounded by subsequent treatment	Yes	No
Involves subjective	No	Yes

[2] *See, generally,* dictionary published by National Cancer Institute for definitions of these and other terms, available at http://cancer.gov/dictionary.

judgment?		

44. Overall survival is considered to be the "gold standard" for clinical trials. That is because, ultimately, patients are concerned with living longer. As Derek Lowe, a journalist following the pharmaceutical industry, noted: "progression-free survival does not necessarily mean 'survival', not in the sense that cancer patients and their relatives really care about. Dying in the same amount of time, albeit with redistributed tumor tissue, is not the endpoint that people are waiting for."[3]

45. Overall survival is an objective, clinical endpoint. However, establishing advantage in overall survival generally requires a larger patient population and takes much longer to assess, because it can only be measured when a patient dies, even if the patient has completed treatment.

46. Progression-free survival, on the other hand, is often favored by drug companies because it can allow for smaller and cheaper, shorter trials. For progression-free survival in renal carcinoma, the progression of the disease is assessed at regular intervals using radiologic scans. A patient is considered to have achieved "progression-free survival" if she remains alive and the radiologic scans demonstrate that the tumor has not grown more than a pre-specified amount.

47. Progression-free survival is considered a surrogate rather than a pure clinical endpoint, because tumor size is correlated with but not a direct measure of survival. Another disadvantage of progression-free survival is that it relies on human judgment and assessment, and is therefore prone to bias, especially in open label studies, *i.e.,* studies in which researchers and patients know who receives the study drug and who receives the control or placebo drug. TIVO-1 and TIVO-3 were both open label studies.

[3] http://pipeline.corante.com/archives/2012/08/08/does_aveos_tivozanib_work_or_not.php.

48. Because it takes far less time and expense to sufficiently power a clinical trial focusing on progression-free survival than overall survival, the FDA has allowed progression-free survival to serve as a primary endpoint for Phase 3 trials of treatments for renal cell carcinoma. However, the FDA has routinely considered overall survival – the life and death of patients – as a crucial element for approval of renal cell carcinoma treatments, even where progression-free survival was the primary endpoint. As the FDA reiterated in the Advisory Committee Meeting for TIVO-1, it has never approved a renal cell cancer treatment demonstrating lower overall survival.

Tivozanib becomes essential to AVEO's survival

49. AVEO is a biopharmaceutical company incorporated in 2001. The Company is based in Cambridge, Massachusetts and develops and commercializes a portfolio of targeted medicines for oncology and other areas of unmet medical need. AVEO was formerly known as "GenPath Pharmaceuticals, Inc." and changed its name to "AVEO Pharmaceuticals, Inc." in March 2005.

50. Early on, AVEO had limited success with early-stage candidates. AVEO thought it found that breakthrough when it inked a deal in 2006 to license tivozanib from Kirin Brewery Company of Japan.

51. Tivozanib quickly became AVEO's lead product and the focus of its research and development. Tivozanib is an oral inhibitor of the vascular endothelial growth factor ("VEGF") receptors. VEGF is a signal protein produced by cells that stimulates blood vessel creation. When overexpressed, VEGF can contribute to the growth of cancerous tumors, because solid cancers cannot grow beyond a limited size without an adequate blood supply.

52. Drugs which inhibit VEGF receptors have been approved as targeted treatments for renal cell carcinoma since 2005, replacing cytokine therapy such as interferon-alpha and

interleukin-2, and systemic therapies such as chemotherapy. Approved anti-VEGF drugs for the treatment of renal cell carcinoma include sorafenib, sutinib, and pazopanib, among others. AVEO sought to gain approval and commercialize tivozanib as a competitor to these established first-line therapies.

53. When the FDA rejected AVEO's first NDA for tivozanib in May 2013 the stock plummeted. When Defendant Bailey took over as president and chief executive officer in January of 2015, he knew the company's success during his tenure centered on tivozanib. For example, at the BIO CEO & Investor Conference on February 9, 2016 ("February 2016 Investor Conference"), he outlined how tivozanib as necessary for value creation, calling it "the central focus of our strategy."

54. Without positive news from a new tivozanib trial, the stock had trouble recovering from the drop it took after TIVO-1. Throughout the Class Period, when TIVO-3 was being planned or ongoing, AVEO received notices from NASDAQ because it had trouble hitting the $1 threshold required for a stock to remain listed on NASDAQ and therefore was at risk of being delisted.

55. Tivozanib had been approved in some other countries but overseas sales were not enough to keep AVEO afloat. All the company's hopes were pinned on TIVO-3 and its success.

TIVO-3 and its Announcement

56. AVEO had other drugs in its pipeline. However, the focus of the company, as reported by the company itself in its SEC filings, was developing tivozanib.

57. According to Defendant Bailey at the February 2016 Investor Conference, in April of 2015, they brought the FDA the design of the study that would be known as TIVO-3. TIVO-3 is a third-line study, meaning the study focuses on the patient population for which two prior lines of treatment have not worked.

58. Whereas TIVO-1 had over 500 enrollees, TIVO-3 was designed to have 351. As TIVO-1 was, TIVO-3 is a Phase 3, open-label, randomized, controlled, multi-national, multi-center, parallel-arm study comparing tivozanib to sorafenib in subjects with RCC. Unlike with TIVO-1, no "crossover" was allowed in TIVO-3, meaning that patients who were randomized to the sorafenib arm could not switch over to the tivozanib after radiographic confirmation of disease progression.

59. After emphasizing how important the drug and the trial were to AVEO, Defendant Bailey represented AVEO's communications with the FDA at the February 2016 Investor Conference as follows:

> We got the Complete Response Letter from the FDA. They said, do another study with PFS as the primary endpoint and will give us assurances that overall survival is not an issue; there is not a safety issue with Tivozanib.
>
> So we brought to them in April this study design which is a third-line study design, which will be less expensive, it will be quicker to read out the data, but we think has a high probability of success. So we asked them three questions: Does this study design meet the requirements that you requested when you said, "Do another study?" The answer was, yes. We asked the second question: Would this study support a registration path forward in third-line RCC? The answer was, "It's subject to risk benefit". But everything is subject to risk benefit. And then we asked, "Would this third-line study support AVEO's proposal for a first-line?" And they said, "That's a review issue".
>
> Now let me be clear; the FDA is not shy to say no. We did consult with outside ex-FDA alumni and said, "Should we be asking for more?" They said, "This is all you are going to get". At the end of the day we need to demonstrate that Tivozanib can win again on PFS and then show a positive trend in overall survival.

60. But even with the less expensive study model, the company still did not have the money to fund TIVO-3. Therefore, in May 2016, AVEO announced it had entered into a private placement of 17,642,482 units, consisting of one share of common stock and a warrant to purchase one share of common stock, at a price of $0.965 per unit, for gross proceeds of approximately $17 million. Concurrent with this private placement, the company also

announced it had borrowed an additional $5 million from Hercules Capital, Inc. ("Hercules"). These funds were needed to fund TIVO-3 and other possible studies with tivozanib.

61. On May 26, 2016, shortly after the announcement of this influx of funds, AVEO announced ("May 26 Press Release") the first patient had been dosed in TIVO-3.

62. AVEO announced in the May 26 Press Release:

> The Phase 3 trial is expected to enroll approximately 322 patients with recurrent or metastatic RCC who have failed at least two prior regimens, including VEGFR-TKI therapy (other than sorafenib). . . Patients will be randomized 1:1 to receive either tivozanib or sorafenib, with no crossover between arms. The primary endpoint of the study is progression free survival. Secondary endpoints include overall survival, overall response rate, and safety and tolerability. Top line readout of the study is currently projected for the first quarter of 2018.
>
> The TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of RCC, is designed to support a first and third line indication for tivozanib in the U.S.

63. At no point did AVEO ever disclose why the number of patients enrolled dropped from the 351 expected enrollees.

64. At that time, Defendant Bailey stressed how important TIVO-3 was to the company. In the May 26 Press Release, he said: "Launch of the pivotal TIVO-3 trial marks a vital step forward for our North American development and registration strategy for tivozanib, and is a defining moment in the turnaround story unfolding at AVEO."

65. For the remainder of 2016, all of AVEO's public filings stressed the importance of tivozanib and reiterated that TIVO-3 was designed to address the OS concerns from the TIVO-1 trial.

66. On February 9, 2017 ("February 9 Press Release"), AVEO furthered buoyed expectations of TIVO-3 by issuing a release that stated that the study was "enrolling substantially ahead of schedule." Enrollment was now expected to be completed by June 2017, two months

ahead of schedule. Because the study is event driven, AVEO did not revise the anticipated timing for topline data but instead reiterated that it was expected in the first quarter of 2018.

67. In the February 9 Press Release, Defendant Bailey said: "The rapid pace of enrollment in our TIVO-3 study is a testament to the broad level of support and enthusiasm for tivozanib among investigators."

68. Two weeks later, AVEO announced ("February 23 Press Release") that TIVO-3 had "successfully completed the first safety review by the study's Safety Monitoring Committee (SMC). The SMC concluded that no safety concern was observed for tivozanib and recommended that the study replace the small number of patients who dropped out prior to starting treatment."

69. The February 23 Press Release stated that, even with the replacement of certain patients, enrollment would be completed in June and topline results would be available in the first quarter of 2018.

70. Defendant Needle is quoted in the February 23 Press Release, lauding tivozanib's ability "to reduce off target toxicity, thereby increasing tolerability" and stating that he was "pleased" that TIVO-3 had "completed its first safety review."

71. AVEO soon again needed to raise money to keep TIVO-3 going. The company announced on March 28, 2017 that it intended to offer and sell shares as an underwritten public offering. The proceeds were to be used for working capital and general corporate purposes, including development and pre-commercial expenses incurred in connection with TIVO-3.

Defendants Take Shortcuts on TIVO-3 Without Proper Disclosure

72. AVEO knew it needed to keep TIVO-3 on track or else risk scaring its investors. For a company starved of money, it couldn't risk raising any flags about TIVO-3. Investors were still hurting from their experience with TIVO-1.

73. Therefore, AVEO kept announcing topline data for TIVO-3 would be available in the first quarter of 2018. The Company continually stressed that TIVO-3 had passed an initial safety data assessment.

74. A poster presented at a meeting for the American Society of Clinical Oncology Annual Meeting in June 2017, AVEO stated TIVO-3 had enrolled 322 patients (161 for tivozanib, 161 for sorafenib) and a total of 255 PFS events would provide 90% power to detect a statistically significant difference in PFS, as assessed by the Independent Radiological review, between the two treatment arms based on a series of stated assumptions.

75. On June 20, 2017, AVEO announced TIVO-3 reached its target enrollment of 322 patients. Defendant Bailey called it a "meaningful milestone for AVEO." Notably, despite the FDA complaining about the geographic distribution of TIVO-1 enrollees, AVEO did not announce the number of TIVO-3 patients from each country. The Company again reiterated that a readout would come in the first quarter of 2018.

76. Shortly after this announcement, AVEO's stock price began to reach over the $1 mark, where it would stay until the end of the Class Period.

77. All through 2017, when speaking on the timing of data analysis, Defendants represented to the public that topline data from the TIVO-3 trial would be available in the first quarter of 2018.

78. It was not until February the Company decided to change the guidance presented to second quarter of 2018.

79. On February 14, 2018, Defendant Bailey spoke at the Leerink Partners 7th Annual Global Healthcare Conference ("February Leerink Conference") and explained the importance of 90% power: "I think from our point of view we've overpowered this study and very candidly,

the reason for overpowering it because we're not going to get a third shot. So this is it, we got to hit it out of the park here, or I think we're going to be an uphill battle with regard to tivozanib."

80. In order to keep that 90% power, TIVO-3 had to hit 255 PFS events. Any less and the power would be reduced.

81. In public filings and press releases in mid-March the company continued to assure investors that this 255 event milestone was coming soon and data would be available in the second quarter.

82. On April 10, 2018, Defendant Bailey spoke at the H.C. Wainwright Global Life Sciences Conference ("April Wainwright Conference") and specifically addressed why powering the study at 90% was so important. He said: "Well, very keenly, we can't afford for this study to fail. So, we're not going to get a third shot. So, we wanted to really power this as robustly as we possibly can."

83. In May, AVEO finally told the public that topline data was not coming in the second quarter, but stated it would instead be coming in the third.

84. On June 7, 2018, Defendant Bailey spoke at the Jefferies 2018 Healthcare Conference. In this talk, he not only pointed to crossover as the problem that led to the poor OS statistic in TIVO-1, but also blamed Russia. He explained TIVO-3 was enrolling patients from just North America and [Western and Central] Europe because TIVO-1 was largely enrolled in Russia and there was "something kind of inconsistent with the Russian subset." As a dutiful AVEO officer, he stressed the supposed safety of tivozanib and how optimistic the company was about it.

85. On July 19, 2018, AVEO again shifted the timing of the data, this time to fourth quarter. AVEO stated that this change was due to "PFS events occurring slower than forecasted,

combined with ten patients being removed or 'censored' from the PFS event count." The release stated that the company was waiting until 255 PFS events had occurred. As of July 18, 2018, according to the release, only 243 events had occurred. There was no mention of any possibility of running the analysis before the 255 events had been reached.

86. There continued to be no mention of possibly running the study before 255 events occurred and it could be powered at 90%. After all, Bailey said the company needed to power the study this way so the drug had an easier time with FDA approval.

87. In August, AVEO again found itself in financial trouble. On August 16, 2018, the Company announced that it again intended to offer and sell shares of its common stock in an underwritten public offering in order to raise "working capital and general corporate purposes, including development and pre-commercial expenses incurred in connection with" TIVO-3. In so doing it benefited from an artificially inflated stock price.

88. In the October 1 Press Release, AVEO finally announced it had initiated topline analysis of TIVO-3. To assure investors, the company said it had notified the FDA of its plan and also that it was initiating the analysis on the "unanimous recommendation of the independent TIVO-3 Study Steering Committee." However, the study was not as powerful as the company had originally intended. The stated reasons for the prior delays of data release were the company was waiting until they had 255 PFS events. All the prior filings with the SEC stated that the company would report at 255 PFS events. The company still had not hit that mark: it only had 242. This reduced the power of the study from 90% to 88%.

89. The October 1 Press Release tried to explain away the shortcut AVEO was now taking by relying on the Steering Committee:

> The Steering Committee recommendation was preceded by a slowing in the rate of progression free survival (PFS) events in the trial over the last 4-6 months. The

> reasons given by the Steering Committee for the unanimous recommendation were that current patients have been on study for at least one year and may not progress for some time, and that the small reduction in events at the time of final analysis was unlikely to materially affect the clinical interpretation of the results.

90. In other words, AVEO admitted that 4-6 months ago progression free survival events had slowed, even though the Company had never previously told investors any sort of slowing meant running the topline analysis before 255 PFS events had occurred was a possibility.

91. By so doing, AVEO essentially admitted its prior statements were materially misleading. The Company kept reassuring investors that they were waiting for 255 PFS events so the drug would have its best chance at FDA approval, but it was not upfront with investors that events had slowed to such a degree that it was considering running the data analysis with fewer events.

92. The October 1 Press Release also did not disclose a reason the number of PFS events had actually gone down since the last announcement. As of the July 19 Press Release, 243 events were announced to have occurred, but the October 1 Press Release stated 242 events had occurred.

93. Nowhere did AVEO acknowledge to investors that the company knew this change would possibly damage its chances with the FDA. After all, at the February Leerink Conference and the April Wainwright Conference, Defendant Bailey had acknowledged the power of the study was extremely important. For example, at the February Leerink Conference, he stated the company had to "hit it out of the park here" or it was going to "an uphill battle with regard to tivozanib."

94. In the October 1 Press Release Defendant Bailey stated that the initiation of this analysis brought the company "one step closer to potentially realizing the strategy [it] laid out in

2015." He, as always, sounded an encouraging note, stating: "TIVO-3 has the potential to serve as the first prospective Phase 3 randomized dataset in this setting, creating an evidence-based guidepost for sequencing therapies in refractory disease**.** We look forward to announcing the topline results of TIVO-3 in the coming weeks."

95. The market reacted negatively to the news that AVEO was going to run an internal topline data analysis with less data than expected—there was a higher-than-normal trading volume and a drop of approximately 10%. On October 1, 2018, AVEO shares closed at $2.97, down from an opening price of $3.43.

96. On October 3, 2018, Defendants Bailey and Dallas spoke at the Leerink Partners Roundtable Series: Rare Disease & Oncology ("October Leerink Conference"). Defendant Bailey defended the decision to conduct the analysis with less data, stating that he "[felt] that that small change in the power would not be material in the end results in our – again, steering committee felt that it's not going to impact the clinical interpretation."

97. At the October Leerink Conference, Defendant Bailey was questioned about why there was a drop in the number of events previously announced from 243 to 242. Defendant Bailey stated it was the result of a patient being censored as "part of the process of cleaning the data."

98. Defendant Bailey—who had been far from transparent regarding when the topline analysis would be done and whether there was a possibility to do it with fewer events—then stated that AVEO had been "very transparent in our discussions about what's happening" because transparency was "important" to the company.

AVEO Falsely Bolsters Investors' Confidence

99. On November 5, 2018, AVEO announced that tivozanib had successfully "met its primary endpoint of demonstrating a statistically significant benefit in progression-free survival

(PFS)" through the TIVO-3 trial. According to the November 5 Press Release, AVEO planned to submit an NDA to the FDA in approximately six months based on results from the TIVO-3 trial, together with the previously completed Phase 3 TIVO-1 trial of tivozanib in the first line treatment of RCC.

100. Notably, the November 5 Press Release downplayed the significance of tivozanib's OS, which AVEO repeatedly asserted in its SEC filings "[t]he TIVO-3 clinical trial was designed to address." The November 5 Press release stated, in relevant part:

> The analysis of the secondary endpoint of overall survival (OS) was not mature at the time of the final PFS analysis, with only 46% of potential OS events having been reported. ***At the time of the preliminary OS analysis, no statistically significant difference in OS was observed*** (HR=1.06, p=0.69). The final survival analysis per protocol is planned for August 2019, two years following the last patient enrolled. Detailed results of the trial will also be submitted for presentation at an upcoming major medical meeting. ***The secondary endpoint of overall response rate for patients receiving tivozanib was 18% compared to 8% for patients receiving sorafenib*** (p=0.02).
>
> ***Tivozanib was generally well-tolerated***, with grade 3 or higher adverse events consistent with those observed in previous tivozanib trials. Infrequent but severe adverse events reported in greater number in the tivozanib arm were thrombotic events similar to those observed in previous tivozanib studies. The most common adverse event in patients receiving tivozanib was hypertension, an adverse event known to reflect effective VEGF pathway inhibition.
>
> ***Based on results from the TIVO-3 trial***, together with the previously completed [and unsuccessful] Phase 3 TIVO-1 trial of tivozanib in the first line treatment of RCC, ***the Company's goal is to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in approximately six months***.

(Emphasis added). The November 5 Press Release thus signaled to investors that, based on the new results from the TIVO-3 trial, and as taken together with the previous TIVO-1 trial's unacceptable results, AVEO was confident enough to file a new NDA with the FDA to seek approval of its lead drug candidate, tivozanib, *within six months*.

101. In fact, Defendant Bailey seemed to signal to investors that AVEO was basically guaranteed approval of tivozanib. He is quoted in the release as saying: "Our determination to

fight for tivozanib in 2015, when AVEO faced an important strategic crossroads, came from our belief that it could have a meaningful impact not just on how a disease was treated, but also what the patient experiences through that treatment. Today's outcome is the culmination of that multi-year effort, and a first step in our goal to improve both outcomes and patient experience."

102. This was despite the fact that the FDA had previously explained to AVEO during the TIVO-1 advisory committee meeting that: "[The] FDA has consistently informed sponsors in meetings and public presentations that while FDA will accept PFS as the primary endpoint for certain disease settings, overall survival remains an important efficacy and safety endpoint. PFS may serve as a primary endpoint in trials for practical reasons, but overall survival is considered to be of ultimate clinical benefit." And TIVO-3 still had a hazard ratio of >1.

103. Additionally, while recognizing that there were severe adverse events in the tivozanib arm, AVEO chose to downplay those by referring to the drug as "well-tolerated." This despite the fact that there were significant hypertensive events on the tivozanib arm. AVEO was again, as it had with TIVO-1, painting an overly hopeful picture for investors.

104. On a conference call with investors that same day ("November 5 Conference Call"), AVEO and Defendants Bailey and Needle continued to mislead investors. Defendant Bailey stated: "TIVO-3 was conducted in response to, and consistent with, the FDA's suggestion to do a second phase 3 study following TIVO-1. They recommended that AVEO conduct an additional clinical study to confirm the progression pre-survival result and provide reassurance that there is no adverse effect on overall survival, which we designed TIVO-3 to demonstrate."

105. Defendant Needle was also active on the November 5 Conference Call. With regard to OS, he stressed that the difference was not "statistically significant" with a hazard ratio of 1.06 and a p value (the test of the statistical significance of a finding) of 0.69. He went on to

further downplay this data by stating: "Of note, both arms far exceeded historical benchmarks for overall survival in he 3rd and 4th line. . . [O]verall survival was not mature at the time of the final PFS analysis with only 46% of potential OS events reported, representing 161 patients." Defendant Needle told investors the company intended to "present the totality of the data at medical meetings in 2019 and to the extent that there is any meaningful change in OS at that time, we would present those updated data. While we cannot currently make any predictions about what the final OS analysis for TIVO-3 will show, we note that in the access the study, the pivotal trial for Axitinb, which was also compared to Sorafenib, an early cut of the survival data at the time of the primary PFF analysis and about 50% of overall survival events shows a hazard ratio above 1. . . At the final analysis the hazard ratio for both populations was below 1.0." He stated: "Based on the results from the TIVO-3 trial, together with the previously completed TIVO-1 trial of Tivozanib in the first line treatment of RCC, the company's goal is to submit a new drug application to the FDA in approximately six months."

106. Defendant Bailey attempted to bolster investors' confidence by again speaking on the drug's supposed safety and the market for a "tolerable option." He referenced the company's prior failure on its first NDA application and spun it into a positive: "We believe that with a more tolerable option and convenient once a day dosing more patients would elect to undergo additional therapy to continue their fight against this terrible disease. If granted FDA approval, AVEO intends to commercialize Tivozanib on its own. We believe this can be effectively achieved with a commercial organization of approximately 70 sales people. We have the benefit of having prepared to launch Tivozanib in 2013, and while the market has changed since that time, a great deal of those efforts can be leveraged to build up our commercial organization ahead of potential launch."

107. During the Q&A section, an investor asked a question about how the FDA would deal with non-mature data. Defendant Needle sought to reassure the questioner, explaining there would be multiple opportunities to submit more mature OS data to the FDA if needed.

108. Defendant Needle all but ignored the serious adverse events and their potential to impede FDA approval.

109. AVEO and Defendants Needle and Bailey knew that the FDA was concerned with the overall safety profile of tivozanib. That was what the FDA flagged as an issue coming out of the TIVO-1 trial. However, Defendants AVEO, Needle and Bailey painted a rosy picture despite knowing the realties. They knew the FDA would question whether patients were living longer on tivozanib and they knew that the available data showed that patients were in fact not living longer on the drug as compared to how long they were living on the already available comparator drug.

110. Dr. Richard A. Guarino, a renowned expert on the NDA drug approval process and author of the leading guidebook on the topic, "New Drug Approval Process, Fifth Edition" (CRC Press 2009), noted that there was not enough data provided to the public to enable investors to know much about the TIVO-3 study. He stated:[4] "Based on the provided amount of data that AVEO intended to submit in their NDA, I can only hope that the data provided by AVEO contained the information recommended by the FDA based on their review of the TIVO-1 study."

[4] Dr. Guarino was retained by Plaintiff to provide background information on the NDA process at the FDA. Dr. Guarino has over 40 years of industry experience. Dr. Guarino has served as Director of Clinical Research at Sandoz Pharmaceuticals, Inc. (now Novartis), Vice President and Medical Director at USV Pharmaceuticals (later called Revlon Healthcare), and Chief Medical and Regulatory Director of Validus Pharmaceutical LLC. For more than thirty years, he has consulted with numerous pharmaceutical companies of all sizes regarding clinical research, FDA regulatory process, and other related topics. He has been an Associate Professor at Farleigh Dickinson University, served as Director of Medical Education and Director of IND/NDA courses for pharmaceutical industry continuing education firms, and guest lectured on topics regarding clinical research and regulatory compliance at institutions and universities around the world.

111. For the remainder of the year, AVEO stressed to investors how happy the Company was with the data and how they intended to file an NDA based on it. For example, a November 9, 2018 press release stressed the "positive topline results" of TIVO-3 while again downplaying the negative OS data by calling it "immature" and saying it "showed no statistically significant difference."

AVEO Fails to Disclose Lost Data

112. In clinical trials, certain enrollees can be "lost to follow-up." This means these were patients at one time were actively participating in the trial, but are now not part of the data set, either because they have become unreachable or because of mechanical error.

113. As TIVO-3 was an open label study, investigators knew who was taking what drug. By mid-2018, investigators also should have known if any enrollees were not properly being followed.

114. AVEO spoke about TIVO-3 many times in 2018. It talked about its data passing internal safety reviews. It never mentioned that its data was incomplete because certain enrollees were lost to follow-up. However, AVEO and its officers must have known by mid-2018 that certain enrollees were not being properly followed by investigators.

The Truth Emerges

115. On January 31, 2019, AVEO issued a timing update for tivozanib, stating, in relevant part:

> [AVEO] has accepted the recommendation of the U.S. Food and Drug Administration (FDA) not to submit a New Drug Application (NDA) for tivozanib (FOTIVDA®) with the preliminary overall survival (OS) results from the Phase 3 TIVO-3 trial***. The FDA indicated that these preliminary OS results do not allay their concerns about the potential detriment in OS outlined in the complete response letter dated June 6, 2013.*** The Company now plans to make a NDA filing decision following the availability of more mature OS results.

(Emphasis added).

116. The release did not say when AVEO learned about this guidance from the FDA or whether it was the first time during the TIVO-3 process that the FDA expressed concern about the necessity to obtain mature OS data before NDA submission given the FDA's previous concern about tivozanib's safety.

117. The timing update proffered excuses for the failed TIVO-3 trial, pointing back to technical information disclosed in the November 5 Press Release:

> ***As disclosed in November 2018, a preliminary analysis of the secondary endpoint of OS in the TIVO-3 trial showed a hazard ratio (HR) > 1.*** The Company previously planned to conduct the final OS analysis in August 2019. ***Due to the longer-than-expected median OS in both arms, and following discussions with the FDA, the Company plans to designate the August 2019 OS analysis as interim.*** Results of this analysis are expected to be reported in the fourth quarter.
>
> ***Since initially conducting the preliminary analysis of the OS endpoint in November 2018, the Company has identified the survival status of a group of patients that were previously lost to follow up. With the identification of these OS events, the October 4, 2018 preliminary OS HR was revised from 1.06 to 1.12. The Company has not performed any OS analyses beyond the preliminary October 4, 2018 data cut-off date.***

(Emphasis added).

118. In other words, the inclusion of data that was somehow "previously lost" increased the hazard ratio for OS by over 5%, making their OS data, which was of prime concern to the FDA, substantially worse. AVEO offered no explanation of how these patients were "previously lost to follow up." They also offered no explanation as to why they previously did not disclose there was missing data.

119. Notably, AVEO did not disclose whether the data they provided to the FDA included this "previously lost to follow-up" data.

120. By making the August analysis an "interim" analysis, AVEO basically was stating that the NDA could not be considered until well after that point. For if AVEO did not have fully mature data, the Company would not be able to answer the FDA's questions.

121. Notably, though not discussed by AVEO, any regulatory filing for tivozanib will now come after FDA approval for other RCC treatments from Pfizer and Merck. Therefore, it is likely that the potential market for tivozanib will shrink.

122. On the news of the delayed NDA filing, AVEO's stock price dropped $1.07 per share, or over 60%, to close at $0.70 per share on January 31, 2019.

Echoes of TIVO-1

123. The news regarding TIVO-3 immediately brings to mind TIVO-1. Like TIVO-3, TIVO-1 was the focus of all of AVEO's attention for a series of years. During TIVO-1, AVEO officers were constantly saying positive things about the prospects of tivozanib and downplaying the significance of the negative OS results. For example, on May 16, 2012, after AVEO already knew the FDA was concerned with the OS results from TIVO-1, AVEO issued a May 16, 2012, the Company issued a materially misleading press release announcing positive findings from TIVO-1 entitled, "Superiority Study of Tivozanib in First-Line Advanced RCC." The press release announced that in TIVO-1, tivozanib had "demonstrated statistically significant and clinically meaningful progression-free survival (PFS) superiority versus an approved targeted agent (sorafenib) in advanced RCC." The May 16, 2012 press release also announced preliminary information regarding overall survival indicating a one-year overall survival rate of 81% for the sorafenib arm versus 77% for the tivozanib arm, but strongly encouraged investors to ignore these results by: (a) characterizing them as "preliminary," "interim" and "not mature" (similar to how they treated to OS results in TIVO-3); (b) claiming that the disparity was caused by subsequent therapy in the sorafenib arm, when that was merely a hypothesis rather than a

proven fact, when in fact the FDA had warned that it was unable to tell whether tivozanib was "toxic"; (c) omitting key regulatory communications expressing concern about overall survival; and (d) omitting that their own scientific misconduct in study design rendered the data uninterpretable.

124. AVEO did not conduct TIVO-1 in the manner discussed and agreed upon with the FDA. Instead, they took three shortcuts which helped speed enrollment, make the study less expensive, and boost results, but compromised its scientific integrity. AVEO did not inform investors of these shortcuts.

125. AVEO also did not inform investors that on May 11, 2012, at a formal meeting held with the U.S. Food & Drug Administration ("FDA") over the new drug application ("NDA") required to be submitted so that tivozanib could be marketed in the United States, the FDA raised concerns about the data they were seeing from TIVO-1. At that meeting, the FDA: (i) recommended that AVEO conduct a whole new well-controlled pivotal clinical trial in an appropriate patient population; (ii) expressed serious concern about the higher death rate in the tivozanib arm of the TIVO-1 study; (iii) criticized the Company's decision to modify TIVO-1 to include a one-way crossover; (iv) questioned whether AVEO should file an NDA at all in light of the compromised TIVO-1 study; and (v) warned that the defective design of the TIVO-1 study made it difficult to tell whether tivozanib was "toxic."

126. In other words, AVEO knew all of this before the May 16, 2012 disclosure but did not inform investors of any of it.

127. While in August 2, 2012, AVEO chose to admit to the public that the FDA had concerns regarding the overall survival ("OS") in TIVO-1, the company failed to disclose that the agency had recommended a second adequately-powered trial in a comparable population,

that the agency questioned whether AVEO should even file an NDA, or that the agency had expressly warned that adverse overall survival trends could affect.

128. AVEO's materially misleading statements regarding TIVO-1 led to SEC charges and civil lawsuits. AVEO agreed to pay a $4 million penalty to settle the SEC's charges against it without admitting or denying the allegations in the complaint. Prior officers either settled or were found guilty in a jury trial. AVEO settled a class action against it related to the TIVO-1 fraud for $15 million and stock worth another $3 million.

129. In the case of TIVO-1, the truth was not revealed until the FDA released its ODAC Briefing Document before the planned advisory committee meeting. It was only then that investors began to realize all AVEO had failed to disclose.

130. AVEO decided to delay TIVO-3 submission and therefore investors do not have access to the FDA's comments about the trial. All investors have is the half-truths provided by AVEO.

Post-Class Period Developments

131. The day following AVEO's announcement, February 1, 2019, HC Wainwright & Co LLC downgraded AVEO from buy to neutral, lowering its target to $1 from a $9 price target it had issued on January 14. Other analysts followed suit.

132. Since the January 31, 2019 announcement of the NDA filing delay, AVEO's stock has only managed to creep above $1 for a handful of days (around an unconfirmed report that AVEO might be purchased by Astrazeneca that appeared on the website *Seeking Alpha* and was subsequently removed).

133. Just as the company had done during TIVO-1, and during the Class Period, AVEO has continued to stress the positive PFS outcome and downplay the OS results. For example, on February 16, 2019, Dr. Brian Rini, principal investigator of the TIVO-3 trial,

presented at the 2019 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium. In an accompanying press release, Defendant Bailey said: "The improvement in progression free survival in the TIVO-3 study, particularly in patients who received prior immunotherapy, is noteworthy. We are hopeful that these positive PFS outcomes translate into an improved overall survival hazard ratio when we report a more mature interim OS outcome in the fourth quarter of 2019. We expect to make a new drug application filing decision following the availability of more mature OS results."

134. During the Class Period, in August 2017, the European Commission granted marketing authorization for tivozanib to AVEO's licensee, EUSA Pharma (UK) Limited ("EUSA"), in all 28 countries of the European Union, Norway and Iceland. Those royalties and related payments were AVEO's only reliable revenue stream. However, on April 3, 2019, the company disclosed that might be in jeopardy because of the negative TIVO-3 results. In an 8-K filed with the SEC on that date, AVEO disclosed:

> As previously disclosed, the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, as part of its post-authorization monitoring procedures, requested the topline data results from our TIVO-3 trial. In addition, the CHMP requested data analyses to explain the discordance between the final progression-free survival ("PFS") results (HR 0.73) and the preliminary OS results (HR 1.12) in the TIVO-3 trial.
>
> Following its review, the CHMP has determined that the analyses of various factors that may have impacted the preliminary OS data do not fully explain the discordance, and that more mature OS data is required prior to drawing a conclusion. Similar to the FDA, the CHMP accepted the proposal to conduct an additional interim OS analysis in August 2019. The CHMP further provided that regulatory action should be considered if the August 2019 interim OS analysis confirms a negative trend in OS.

135. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

DEFENDANTS MAKE MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

136. The Class Period begins on May 4, 2017, when AVEO filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarterly period ending on March 31, 2017 (the "Q1 2017 10-Q"). The Q1 2017 10-Q again touted that the TIVO-3 trial was designed to rectify the earlier shortcomings of the TIVO-1 trial, added more statements regarding safety, and reiterated topline data would be available in Q1 2018:

> We expect to complete enrollment in the TIVO-3 trial in June 2017, and to report top line data in the first quarter of 2018. The TIVO-3 trial passed an initial safety data assessment in February 2017. We expect a pre-planned interim futility analysis to occur mid-year 2017.

137. The Q1 2017 10-Q also contained merely generic, boiler plate representations concerning the risk that tivozanib and its clinical trials might prove unsuccessful, stating, in relevant part:

> The success of tivozanib will depend on several factors, including the following:
>
> - our ability to secure the substantial additional capital required to complete our clinical trials of tivozanib, including the TIVO-3 trial and the TiNivo trial;
> - successful enrollment and completion of clinical trials; [and]
> - a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA or any other comparable foreign regulatory authority for marketing approval[.]
>
> * * *
>
> Many of these factors are beyond our control, including clinical trial results, the regulatory approval process, potential threats to our intellectual property rights and the development, manufacturing, marketing and sales efforts of our collaborators. If we are unable to develop, receive marketing approval for and successfully commercialize tivozanib on our own or with our collaborators, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

138. Appended as exhibits to the Q1 2017 10-Q were signed certifications by Defendants Bailey and Ehrlich pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), certifying that "[t]he [Q1 2017 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934" and that "[t]he information contained in the [Q1 2017 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

139. AVEO and Defendants Bailey and Ehrlich either knew or recklessly disregarded that the statements referenced in ¶¶136-138 were materially misleading when made, *inter alia*, because they knew by May 2017 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

140. In an accompanying May 4, 2017 ("May 4 Press Release") press release, Defendant Bailey again emphasized TIVO-3, stating: "***We strengthened our balance sheet in the first quarter through an underwritten public offering, giving us the resources to potentially fund operations through the readout of our pivotal, Phase 3 TIVO-3 study of tivozanib in renal cell cancer (RCC), expected in the first quarter of 2018***. TIVO-3, which is designed to serve as the basis for a potential U.S. registration of tivozanib as a first- and third-line treatment for RCC, remains on track to complete enrollment and a pre-planned interim futility analysis in June of this year."

141. The May 4 Press Release also repeated: "A pre-planned futility analysis of the trial is expected around midyear 2017, with ***topline data expected in the first quarter of 2018***. The TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first-

line treatment of RCC, is designed to support potential regulatory approval of tivozanib in the U.S. as a third- and first- line treatment for RCC."

142. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶¶140-141 were materially misleading when made, *inter alia*, because they knew by May 2017 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

143. On June 20, 2017, AVEO announced TIVO-3 reached its target enrollment of 322 patients. Defendant Bailey called it a "meaningful milestone for AVEO." Notably, despite the FDA complaining about the geographic distribution of TIVO-1 enrollees, AVEO did not announce the number of TIVO-3 patients from each country. The release also again reiterated that "A pre-planned futility analysis of the TIVO-3 trial is expected around midyear 2017, with ***topline data expected in the first quarter of 2018***." Bailey stated: "As previously noted, based on a recommendation by the Safety Monitoring Committee, the study will continue enrolling additional patients for the next few weeks to replace early dropouts. We look forward to several key upcoming potential inflection points in the tivozanib program, including a European regulatory decision and ongoing enrollment in the TiNivo study, culminating ***in the readout of the TIVO-3 trial, expected in the first quarter of 2018***."

144. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶143 were materially misleading when made, *inter alia*, because they knew by June 2017 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

145. On August 9, 2017, AVEO filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarterly period ending on

June 30, 2017 (the "Q2 2017 10-Q"). The Q2 2017 10-Q again stated the first quarter of 2018 topline data estimate:

> In June 2017, the TIVO-3 trial reached its enrollment target of 322 patients, more than two months ahead of our initial guidance. ***We expect a pre-planned interim futility analysis to occur mid-year 2017. We expect to report topline data from theTIVO-3 trial in the first quarter of 2018.***

146. The Q2 2017 10-Q also contained merely generic, boiler plate representations concerning the risk that tivozanib and its clinical trials might prove unsuccessful, stating, in relevant part:

> The success of tivozanib will depend on several factors, including the following:
>
> - our ability to secure the substantial additional capital required to complete our clinical trials of tivozanib, including the TIVO-3 trial and the TiNivo trial;
> - successful enrollment and completion of clinical trials; [and]
> - a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA or any other comparable foreign regulatory authority for marketing approval[.]
>
> * * *
>
> Many of these factors are beyond our control, including clinical trial results, the regulatory approval process, potential threats to our intellectual property rights and the development, manufacturing, marketing and sales efforts of our collaborators. If we are unable to develop, receive marketing approval for and successfully commercialize tivozanib on our own or with our collaborators, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

147. Appended as exhibits to the Q2 2017 10-Q were signed certifications by Defendants Bailey and Dallas pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), certifying that "[t]he [Q2 2017 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934" and that "[t]he information contained in the [Q2 2017 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

148. AVEO and Defendants Bailey and Dallas either knew or recklessly disregarded that the statements referenced in ¶¶145-147 were materially misleading when made, *inter alia*, because they knew by August 2017 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

149. In a related August 9, 2017 press release, TIVO-3 continued to be front and center for the company. The release again mentioned that "***topline data [was] expected in the first quarter of 2018***." It also again assured investors regarding the study's design: "The TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of RCC, is designed to support an application seeking regulatory approval of tivozanib in the U.S. as a first and third line treatment for RCC."

150. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶149 were materially misleading when made, *inter alia*, because they knew by August 2017 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

151. On October 5, 2017 ("October 5 Press Release"), AVEO again reassured investors with regard to TIVO-3, issuing a release about the completion of the pre-planned futility analysis of TIVO-3. The release stated that, based on the results of the futility analysis, which were reviewed by an independent statistician, the study would continue without modification. In the October 5 Press Release, AVEO again reassured investors that topline data was expected in the first quarter of 2018. It also stated that "the TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of RCC, is designed to support regulatory approval of tivozanib in the U.S. as a first and third line treatment for RCC."

152. In the October 5 Press Release, Defendant Bailey himself reiterated the TIVO-3 data would be available in the first quarter of 2018.

153. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶¶151-152 were materially misleading when made, *inter alia*, because they knew by October 2017 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

154. On November 7, 2017, AVEO filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarterly period ending on September 30, 2017 (the "Q3 2017 10-Q"). The Q3 2017 10-Q still stated that topline data was expected in first quarter 2018:

> The TIVO-3 trial has passed two semi-annual safety data assessments. In June 2017, the TIVO-3 trial reached its enrollment target of 322 patients, more than two months ahead of our initial guidance. In October 2017, we successfully passed a pre-planned interim futility analysis for TIVO-3. Based on the results of the futility analysis, which were reviewed by an independent statistician, the study continued as planned without modification. ***We expect to receive and report topline data from the TIVO-3 trial in the first quarter of 2018***.

(Emphasis added).

155. The Q3 2017 10-Q also contained merely generic, boiler plate representations concerning the risk that tivozanib and its clinical trials might prove unsuccessful, stating, in relevant part:

> The success of tivozanib will depend on several factors, including the following:
>
> - our ability to secure the substantial additional capital required to complete our clinical trials of tivozanib, including the TIVO-3 trial and the TiNivo trial;
> - successful enrollment and completion of clinical trials; [and]
> - a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA or any other comparable foreign regulatory authority for marketing approval[.]
>
> * * *

> Many of these factors are beyond our control, including clinical trial results, the regulatory approval process, potential threats to our intellectual property rights and the development, manufacturing, marketing and sales efforts of our collaborators. If we are unable to develop, receive marketing approval for and successfully commercialize tivozanib on our own or with our collaborators, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

156. Appended as exhibits to the Q3 2017 10-Q were signed certifications by Defendants Bailey and Dallas pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), certifying that "[t]he [Q3 2017 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934" and that "[t]he information contained in the [Q3 2017 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

157. AVEO and Defendants Bailey and Dallas either knew or recklessly disregarded that the statements referenced in ¶¶154-156 were materially misleading when made, *inter alia*, because they knew by November 2017 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

158. In a related November 7, 2017 press release, Defendant Bailey stated: "The third quarter was a transformative period for AVEO, with the achievement of significant milestones in each of the three pillars of our global strategy for tivozanib. Notably, with the European approval of tivozanib (FOTIVDA®) in advanced RCC, we have transitioned from a development stage company to one with a commercially approved product, a watershed achievement for any emerging life sciences company. In addition, TIVO-3, our U.S. registration study, successfully passed the interim futility analysis with no changes to study protocol." He also again, just a

couple of months before entering first quarter 2018, reiterated that TIVO-3 would have topline results in first quarter 2018.

159. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶158 were materially misleading when made, *inter alia*, because they knew by November 2017 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

160. In a December 7, 2017 release focusing on tivozanib and another drug in AVEO's pipeline, Defendant Bailey was suddenly less specific about when there would be topline data available for TIVO-3, stating: "2018 is expected to be another transformative year, with anticipated top-line results in the TIVO-3 study of tivozanib in third line advanced renal cell carcinoma (RCC). . ." However, he did not correct his earlier statements regarding the data being expected in first quarter of 2018, leading investors to believe there had been no change in the plan.

161. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶160 were materially misleading when made, *inter alia*, because they knew by December 2017 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

162. The following month in a January 2, 2018 release about AVEO's refinancing its existing $20.0 million debt facility with Hercules, Defendant Bailey again was vague about when the topline data would be available, stating: "***We continue to look forward to several potential key developments, including the receipt of top-line results from the TIVO-3 trial of tivozanib in third-line refractory renal cell carcinoma*** and, if positive, the filing of a new drug application with the FDA seeking marketing approval of tivozanib in the United States."

163. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶162 were materially misleading when made, *inter alia*, because they knew by January 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the first quarter of 2018 if the study was to be properly powered.

164. In a February 12, 2018 release regarding the United Kingdom's National Institute for Health and Care Excellence's endorsement of tivozanib for first-line treatment of RCC, Defendant Bailey finally made a disclosure regarding topline data not being available in the first quarter. He stated: "We continue to execute on our strategic plans, and we have had a very productive 2018 thus far, with the recent presentation of positive preliminary data from our tivozanib and nivolumab combination TiNivo study in RCC and an investigator sponsored study of tivozanib in liver cancer. We look forward to several potential additional key milestones in 2018, including further EU reimbursement decisions ***as well as topline data in the second quarter from our Phase 3 TIVO-3 study***."

165. However, this was still misleading. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶164 were materially misleading when made, *inter alia*, because they knew by mid-February 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the second quarter of 2018 if the study was to be properly powered.

166. On February 14, 2018, Defendant Bailey spoke at the Leerink Partners 7th Annual Global Healthcare Conference ("February Leerink Conference"). During the talk, Defendant Bailey admitted that, since he took over the company in 2015, AVEO was focused on showing that the higher incidence of deaths seen in TIVO-1 was purely the result of crossover and not because of toxicity issues with the drug itself. Only when pushed by the questioner, did

Defendant Bailey admit there might be other reasons for the higher death rate than crossover alone. He said:

> Yeah, I mean, you can't definitively exclude that there's not some late safety issue that is the cause. I mean, I would be remiss to suggest that there's no way that could be the case. And really this is why we're doing the TIVO-3 study because we're going to try to show that. One little known fact that did contribute in some way potentially to the overall survival was the result. There was also an imbalance in ECOG that favored sorafenib. So more patients on the sorafenib are where ECOG zero, then ECOG one, compared to the TIVO arm. And that's a prognostic factor or score, so that could have had an effect. But it certainly wouldn't explain the whole thing.

167. During the February Leerink Conference, Defendant Bailey specifically addressed why powering the study at 90% was so important. He explained:

> I'll start by saying we practice realistic optimism when it comes to the power. ***I think from our point of view we've overpowered this study and very candidly, the reason for overpowering it because we're not going to get a third shot. So this is it, we got to hit it out of the park here, or I think we're going to be an uphill battle with regard to tivozanib***.
>
> So to the specific question for powering, we powered it after PFS, it's not powered for overall survival. Again, we only need to show a trend, we don't have to show statistical significance there. As far as powering assumptions it is 90% powered to show the difference between four and six months of progression-free survival.

168. On March 13, 2018, AVEO filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the fiscal year ending on December 31, 2017 (the "2017 10-K"). As with the Company's previous filings referenced above, the 2017 10-K represented that the TIVO-3 trial was designed to rectify the earlier shortcomings of the TIVO-1 trial results in 2013. This was the first annual report to state that AVEO intended to wait until 255 PFS results to run the topline analysis. It also touted safety results:

> The TIVO-3 trial has enrolled a total of 351 patients and has passed three semi-annual safety data assessments. In October 2017, we successfully passed a pre-planned interim futility analysis for TIVO-3. Based on the results of the futility

> analysis, which were reviewed by an independent statistician, the trial continued as planned without modification. ***We expect to receive and report topline data from the TIVO-3 trial (including PFS and preliminary OS data) in the second quarter of 2018, approximately 8-10 weeks after the 255th event (progression determined by an independent radiology committee or death) is reported***.

169. The 2017 10-K also contained the same merely generic, boiler plate representations as the Q2 2016 10-Q and 2016 10-K regarding the risk that tivozanib and its clinical trials might prove unsuccessful, including: (i) the Company's "ability to secure the substantial additional capital required to complete our clinical trials of tivozanib, including the TIVO-3 trial and the TiNivo trial;" (ii) "successful enrollment and completion of clinical trials;" and (iii) "a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA or any other comparable foreign regulatory authority for marketing approval[.]"

170. Appended as exhibits to the 2017 10-K were signed SOX certifications by Defendants Bailey and Dallas certifying that "[t]he [2017 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934" and that "[t]he information contained in the [2017 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

171. At no point did AVEO explain how it went from announcing it had only enrolled 322 patients to stating it had enrolled 351 (which was the target when the study was announced).

172. AVEO and Defendants Bailey and Dallas either knew or recklessly disregarded that the statements referenced in ¶¶168-170 were materially misleading when made, *inter alia*, because they knew by March 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the second quarter of 2018 if the study was to be properly powered.

173. In a related March 13, 2018 press release, again assured investors that topline data was coming soon: "***Based on the current rate of progression-free survival (PFS) events, the***

Company expects the TIVO-3 trial to read out in the second quarter of 2018. The TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first line treatment of aRCC [advanced RCC], is designed to support a potential regulatory approval of tivozanib in the U.S. as a first- and third-line treatment for aRCC."

174. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶173 were materially misleading when made, *inter alia*, because they knew by March 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the second quarter of 2018 if the study was to be properly powered.

175. On March 21, 2018 ("March 21 Press Release"), AVEO announced data from a TIVO-1 follow-up study, which had no control arm. Defendant Needle used the March 21 Press Release as another opportunity to praise the alleged safety of tivozanib. He stated in the release: "We believe these efficacy and safety findings in refractory patients support the rationale for our ongoing Phase 3 TIVO-3 study. We anticipate that the results of the TIVO-3 study, together with the results of the previously completed TIVO-1 trial of tivozanib in the first-line treatment of aRCC, will serve as a key component for a potential regulatory approval of tivozanib in the U.S. as a first- and third-line treatment for aRCC. When completed, TIVO-3 will be among the only large randomized datasets in third-line disease, a sizable and growing treatment segment thanks to advances in earlier lines of treatment, and in patients progressing on prior immunotherapy. Based on the current rate of progression-free survival events***, we expect top-line results from this study to read out in the second quarter of this year***."

176. AVEO and Defendant Needle either knew or recklessly disregarded that the statements referenced in ¶175 were materially misleading when made, *inter alia*, because they

knew by March 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the second quarter of 2018 if the study was to be properly powered.

177. At the April Wainwright Conference, Defendant Bailey specifically addressed why powering the study at 90% was so important. He said: "Well, very keenly, we can't afford for this study to fail. So, we're not going to get a third shot. So, we wanted to really power this as robustly as we possibly can."

178. At the April Wainwright Conference, Defendant Bailey also assured the audience that topline data was expected in the "***second quarter of 2018***."

179. AVEO and Defendant Needle either knew or recklessly disregarded that the statements referenced in ¶¶177-178 were materially misleading when made, *inter alia*, because they knew by April 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the second quarter of 2018 if the study was to be properly powered.

180. On May 8, 2018, AVEO filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarterly period ending on March 31, 2018 (the "Q1 2018 10-Q"). The Q1 2018 10-Q again touted that the TIVO-3 trial was designed to rectify the earlier shortcomings of the TIVO-1 trial, but now amended when topline data would be available:

> The trial has passed three semi-annual safety data assessments, and in October 2017, TIVO-3 successfully passed a pre-planned interim futility analysis. Based on the results of the futility analysis, which were reviewed by an independent statistician, the trial continued as planned without modification. ***We expect to receive and report topline data from the TIVO-3 trial (including PFS and preliminary OS data) in the third quarter of 2018, approximately 6-8 weeks after the trial records the 255 th PFS event (progression determined by an independent radiology committee or death).***

(Emphasis added).

181. The Q1 2018 10-Q also contained merely generic, boiler plate representations concerning the risk that tivozanib and its clinical trials might prove unsuccessful, stating, in relevant part:

> The success of tivozanib will depend on several factors, including the following:
>
> - our ability to secure the substantial additional capital required to complete our clinical trials of tivozanib, including the TIVO-3 trial and the TiNivo trial;
> - successful enrollment and completion of clinical trials; [and]
> - a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA or any other comparable foreign regulatory authority for marketing approval[.]
>
> * * *
>
> Many of these factors are beyond our control, including clinical trial results, the regulatory approval process, potential threats to our intellectual property rights and the development, manufacturing, marketing and sales efforts of our collaborators. If we are unable to develop, receive marketing approval for and successfully commercialize tivozanib on our own or with our collaborators, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

182. Appended as exhibits to the Q1 2018 10-Q were signed certifications by Defendants Bailey and Dallas pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), certifying that "[t]he [Q1 2018 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934" and that "[t]he information contained in the [Q1 2018 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

183. AVEO and Defendants Bailey and Dallas either knew or recklessly disregarded that the statements referenced in ¶¶180-182 were materially misleading when made, *inter alia*, because they knew by May 2018 that (i) PFS events were not occurring rapidly enough for the company to receive topline data in the third quarter of 2018 if the study was to be properly

powered; and (ii) certain enrollees had been lost to follow-up and were not being considered by investigators.

184. In a related May 8, 2018 press release ("May 8 Press Release"), AVEO explicitly addressed the fact that TIVO-3 data was not coming in the second quarter of 2018. Clearly knowing that investors would be getting restless, AVEO announced "***the pre-specified number of progression free survival (PFS) events required to trigger data analysis of the Phase 3 TIVO-3 trial have not been reached at this time***." Therefore, the company revised its guidance and stated data was now anticipated in the third quarter. Just as the company had done with TIVO-1, AVEO began to take shortcuts, announcing that "[i]n collaboration with the CRO [contract *research* organization] conducting the TIVO-3 study, AVEO has taken measures to shorten the data cleaning and analysis period following the pre-specified events trigger from 8-10 weeks down to 6-8 weeks."

185. In the May 8 Press Release, Defendant Bailey stated: "***We continue to work toward reporting topline results from our Phase 3 TIVO-3 Study, which we now anticipate will occur in the third quarter of 2018***. We are working closely with our contract research organization (CRO) to shorten the time required to do the data cleaning and analysis upon reaching the requisite number of events. Together with the TIVO-1 study, the TIVO-3 study has been designed to serve as the basis for a potential U.S. approval of tivozanib as a first- and third-line treatment for advanced renal cell carcinoma (aRCC)."

186. The May 8 Press Release did not contain any disclosure about possibly running the data analysis prior to 255 PFS events being reached, nor a disclosure about lost enrollees.

187. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶¶184-185 were materially misleading when made, *inter alia*, because

they knew by May 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the third quarter of 2018 if the study was to be properly powered; and (ii) certain enrollees had been lost to follow-up and were not being considered by investigators.

188. On July 19, 2018 ("July 19 Press Release"), AVEO issued yet another press release reporting a delay of TIVO-3 data, this time shifting its release to fourth quarter of 2018. AVEO stated that this change was due to "PFS events occurring slower than forecasted, combined with ten patients being removed or 'censored' from the PFS event count." The release stated that the company was waiting until 255 PFS events had occurred. As of July 18, 2018, according to the release, only 243 events had occurred. According to AVEO, this delay would not affect the "intended statistical powering of the study."

189. The July 19 Press Release did not contain any disclosure about possibly running the data analysis prior to 255 PFS events being reached, nor a disclosure about lost enrollees.

190. AVEO either knew or recklessly disregarded that the statements referenced in ¶188 were materially misleading when made, *inter alia*, because they knew by July 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the fourth quarter of 2018 if the study was to be properly powered; and (ii) certain enrollees had been lost to follow-up and were not being considered by investigators.

191. On August 7, 2018, AVEO filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarterly period ending on June 30, 2018 (the "Q2 2018 10-Q"). The Q2 2018 10-Q contained no new disclosure regarding when the topline analysis would be done:

> The TIVO-3 trial enrolled a total of 351 patients. The trial has passed three semi-annual safety data assessments, and in October 2017, TIVO-3 successfully passed a pre-planned interim futility analysis. Based on the results of the futility analysis, which were reviewed by an independent statistician, the trial continued

> as planned without modification. ***We expect to report topline results from the TIVO-3 study (including PFS and preliminary OS data) in the fourth quarter of 2018, approximately 6-8 weeks after the trial records 255 PFS events. We plan to announce when 255 PFS events have occurred and the topline data analysis for the trial has been initiated***.

(Emphasis added).

192. The Q2 2018 10-Q also contained merely generic, boiler plate representations concerning the risk that tivozanib and its clinical trials might prove unsuccessful, stating, in relevant part:

> The success of tivozanib will depend on several factors, including the following:
>
> - our ability to secure the substantial additional capital required to complete our clinical trials of tivozanib, including the TIVO-3 trial and the TiNivo trial;
> - successful design, enrollment and completion of clinical trials; [and]
> - a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA or any other comparable foreign regulatory authority for marketing approval[.]
>
> * * *
>
> Many of these factors are beyond our control, including clinical trial results, the regulatory approval process, potential threats to our intellectual property rights and the development, manufacturing, marketing and sales efforts of our collaborators. If we are unable to develop, receive marketing approval for and successfully commercialize tivozanib on our own or with our collaborators, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

193. Appended as exhibits to the Q2 2018 10-Q were signed certifications by Defendants Bailey and Dallas pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), certifying that "[t]he [Q2 2018 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934" and that "[t]he information contained in the [Q2 2018 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

194. At no point did AVEO explain how it went from announcing it had only enrolled 322 patients to stating it had enrolled 351 (which was the target when the study was announced).

195. The Q2 2018 10-Q did not contain any disclosure about possibly running the data analysis prior to 255 PFS events being reached, nor a disclosure about lost enrollees.

196. AVEO and Defendants Bailey and Dallas either knew or recklessly disregarded that the statements referenced in ¶¶191-193 were materially misleading when made, *inter alia*, because they knew by June 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the fourth quarter of 2018 if the study was to be properly powered; and (ii) certain enrollees had been lost to follow-up and were not being considered by investigators.

197. In the related August 7, 2018 press release, Defendant Bailey emphasized that TIVO-3 "has the potential to serve as a benchmark study for the sequencing of therapies in advanced disease."

198. The release also stated:

> As previously announced, the Company expects to report topline results from the TIVO-3 study, ***AVEO's Phase 3 trial of tivozanib as a third-line treatment for advanced renal cell carcinoma (aRCC), in the fourth quarter of 2018, approximately 6-8 weeks after the trial records 255 progression free survival (PFS) events. AVEO plans to announce when 255 PFS events have occurred and the topline data analysis for the trial has been initiated***. Together with the TIVO-1 study, TIVO-3 is designed to serve as the basis for a potential U.S. approval of tivozanib (FOTIVDA®) as a first- and third-line treatment for aRCC.

199. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶197 were materially misleading when made, *inter alia*, because they knew by August 2018 that PFS events were not occurring rapidly enough for the company to receive topline data in the fourth quarter of 2018 if the study was to be properly powered.

200. Later in August AVEO again found itself in financial trouble. On August 16, 2018, the company announced that it again intended to offer and sell shares of its common stock in an underwritten public offering in order to raise "working capital and general corporate purposes, including development and pre-commercial expenses incurred in connection with" TIVO-3. In so doing it benefited from an artificially inflated stock price.

201. In the October 1 Press Release, AVEO finally announced it had initiated topline analysis of TIVO-3. To assure investors, the company said it had notified the FDA of its plan and also that it was initiating the analysis on the "unanimous recommendation of the independent TIVO-3 Study Steering Committee." However, the study was not as powerful as the company had originally intended. The stated reasons for the prior delays of data release were the company was waiting until they had 255 PFS events. All the prior filings with the SEC stated that the company would report at 255 PFS events. The company still had not hit that mark: it only had 242. This reduced the power of the study from 90% to 88%.

202. The October 1 Press Release tried to explain away the shortcut AVEO was now taking by relying on the Steering Committee:

> The Steering Committee recommendation was preceded by a slowing in the rate of progression free survival (PFS) events in the trial over the last 4-6 months. The reasons given by the Steering Committee for the unanimous recommendation were that current patients have been on study for at least one year and may not progress for some time, and that the small reduction in events at the time of final analysis was unlikely to materially affect the clinical interpretation of the results.

203. In other words, AVEO admitted that 4-6 months ago progression free survival events had slowed, a fact that they previously did not say would limit the ability of the trial to hit 255 events. Of course, what the release did not say was that AVEO knew it needed to announce data, whether properly powered or not, or else risk losing the company entirely.

204. The October 1 Press Release also did not disclose a reason the number of PFS events had actually gone down since the last announcement. As of the July 19 Press Release, 243 events were announced to have occurred, but the October 1 Press Release stated 242 events had occurred. It also did not reveal that enrollees were lost to follow-up.

205. In the October 1 Press Release Defendant Bailey stated that the initiation of this analysis brought the company "one step closer to potentially realizing the strategy [it] laid out in 2015." He, as always, sounded an encouraging note, stating: "TIVO-3 has the potential to serve as the first prospective Phase 3 randomized dataset in this setting, creating an evidence-based guidepost for sequencing therapies in refractory disease**.** We look forward to announcing the topline results of TIVO-3 in the coming weeks."

206. Nowhere did AVEO acknowledge to investors that the company knew this change would possibly damage its chances with the FDA. After all, at the February Leerink Conference and the April Wainwright Conference, Defendant Bailey had acknowledged the power of the study was extremely important. For example, at the February Leerink Conference, he stated the company had to "hit it out of the park here" or it was going to "an uphill battle with regard to tivozanib."

207. The market reacted negatively to this news, with a higher-than-normal trading volume and a drop of approximately 10%. On October 1, 2018, AVEO shares closed at $2.97, down from an opening price of $3.43.

208. On November 5, 2018, AVEO announced that tivozanib had successfully "met its primary endpoint of demonstrating a statistically significant benefit in progression-free survival (PFS)" through the TIVO-3 trial. According to the November 5 Press Release, AVEO planned to submit an NDA to the FDA in approximately six months based on results from the TIVO-3

trial, together with the previously completed Phase 3 TIVO-1 trial of tivozanib in the first line treatment of RCC.

209. Notably, the November 5 Press Release downplayed the significance of tivozanib's OS, which AVEO repeatedly asserted in its SEC filings "[t]he TIVO-3 clinical trial was designed to address." The November 5 Press release stated, in relevant part:

> The analysis of the secondary endpoint of overall survival (OS) was not mature at the time of the final PFS analysis, with only 46% of potential OS events having been reported. ***At the time of the preliminary OS analysis, no statistically significant difference in OS was observed*** (HR=1.06, p=0.69). The final survival analysis per protocol is planned for August 2019, two years following the last patient enrolled. Detailed results of the trial will also be submitted for presentation at an upcoming major medical meeting. ***The secondary endpoint of overall response rate for patients receiving tivozanib was 18% compared to 8% for patients receiving sorafenib*** (p=0.02).
>
> ***Tivozanib was generally well-tolerated***, with grade 3 or higher adverse events consistent with those observed in previous tivozanib trials. Infrequent but severe adverse events reported in greater number in the tivozanib arm were thrombotic events similar to those observed in previous tivozanib studies. The most common adverse event in patients receiving tivozanib was hypertension, an adverse event known to reflect effective VEGF pathway inhibition.
>
> ***Based on results from the TIVO-3 trial***, together with the previously completed [and unsuccessful] Phase 3 TIVO-1 trial of tivozanib in the first line treatment of RCC, ***the Company's goal is to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in approximately six months***.

(Emphasis added). The November 5 Press Release thus signaled to investors that, based on the new results from the TIVO-3 trial, and as taken together with the previous TIVO-1 trial's unacceptable results, AVEO was confident enough to file a new NDA with the FDA to seek approval of its lead drug candidate, tivozanib, *within six months*.

210. In fact, Defendant Bailey seemed to signal to investors that AVEO was basically guaranteed approval of tivozanib. He is quoted in the release as saying: "Our determination to fight for tivozanib in 2015, when AVEO faced an important strategic crossroads, came from our belief that it could have a meaningful impact not just on how a disease was treated, but also what

the patient experiences through that treatment. Today's outcome is the culmination of that multi-year effort, and a first step in our goal to improve both outcomes and patient experience."

211. This was despite the fact that the FDA had previously explained to AVEO during the TIVO-1 advisory committee meeting that: "[The] FDA has consistently informed sponsors in meetings and public presentations that while FDA will accept PFS as the primary endpoint for certain disease settings, overall survival remains an important efficacy and safety endpoint. PFS may serve as a primary endpoint in trials for practical reasons, but overall survival is considered to be of ultimate clinical benefit." And TIVO-3 still had a hazard ratio of >1.

212. Nowhere in the release was there any mention that the data was incomplete. Amazingly, despite the fact that AVEO later disclosed it had located patients "previously lost to follow-up," this release contained no disclosure that any patients were lost.

213. Additionally, while recognizing that there were severe adverse events in the tivozanib arm, AVEO chose to downplay those by referring to the drug as "well-tolerated." This despite the fact that there were significant hypertensive events on the tivozanib arm. AVEO was again, as it had with TIVO-1, painting an overly hopeful picture for investors.

214. AVEO and Defendant Baily either knew or recklessly disregarded that the statements referenced in ¶¶208-213 were materially misleading when made, *inter alia*, because (i) tivozanib had insufficient survival data to meet FDA approval following its initial 2013 rejection by the FDA; (ii) the survival data they presented to the public did not include all OS events; and (iii) this lack of sufficient survival data would put tivozanib at greater risk of delayed FDA approval.

215. On a conference call with investors that same day ("November 5 Conference Call"), AVEO and Defendants Bailey and Needle continued to mislead investors. Defendant

Bailey stated: "TIVO-3 was conducted in response to, and consistent with, the FDA's suggestion to do a second phase 3 study following TIVO-1. They recommended that AVEO conduct an additional clinical study to confirm the progression pre-survival result and provide reassurance that there is no adverse effect on overall survival, which we designed TIVO-3 to demonstrate."

216. Defendant Needle was also active on the November 5 Conference Call. With regard to OS, he stressed that the difference was not "statistically significant" with a hazard ratio of 1.06 and a p value (the test of the statistical significance of a finding) of 0.69. He went on to further downplay this data by stating: "Of note, both arms far exceeded historical benchmarks for overall survival in the 3rd and 4th line. . . [O]verall survival was not mature at the time of the final PFS analysis with only 46% of potential OS events reported, representing 161 patients." Defendant Needle told investors the company intended to "present the totality of the data at medical meetings in 2019 and to the extent that there is any meaningful change in OS at that time, we would present those updated data. While we cannot currently make any predictions about what the final OS analysis for TIVO-3 will show, we note that in the access the study, the pivotal trial for Axitinb, which was also compared to Sorafenib, an early cut of the survival data at the time of the primary PFF analysis and about 50% of overall survival events shows a hazard ratio above 1. . . At the final analysis the hazard ratio for both populations was below 1.0." He stated: "Based on the results from the TIVO-3 trial, together with the previously completed TIVO-1 trial of Tivozanib in the first line treatment of RCC, the company's goal is to submit a new drug application to the FDA in approximately six months."

217. Defendant Bailey attempted to bolster investors' confidence by again speaking on the drug's supposed safety and the market for a "tolerable option." He referenced the company's prior failure on its first NDA application and spun it into a positive: "We believe that with a

more tolerable option and convenient once a day dosing more patients would elect to undergo additional therapy to continue their fight against this terrible disease. If granted FDA approval, AVEO intends to commercialize Tivozanib on its own. We believe this can be effectively achieved with a commercial organization of approximately 70 sales people. We have the benefit of having prepared to launch Tivozanib in 2013, and while the market has changed since that time, a great deal of those efforts can be leveraged to build up our commercial organization ahead of potential launch."

218. During the Q&A section, an investor asked a question about how the FDA would deal with non-mature data. Defendant Needle sought to reassure the questioner, explaining there would be multiple opportunities to submit more mature OS data to the FDA if needed.

219. AVEO and Defendants Baily and Needle either knew or recklessly disregarded that the statements referenced in ¶¶215-218 were materially misleading when made, *inter alia*, because (i) tivozanib had insufficient survival data to meet FDA approval following its initial 2013 rejection by the FDA; (ii) the survival data they presented to the public did not include all OS events; and (iii) this lack of sufficient survival data would put tivozanib at greater risk of delayed FDA approval.

220. On November 9, 2018, AVEO filed a Quarterly Report on Form 10-Q with the SEC, announcing the Company's financial and operating results for the quarterly period ending on September 30, 2018 (the "Q3 2018 10-Q"). The Q3 2018 10-Q again touted that the TIVO-3 trial was designed to rectify the earlier shortcomings of the TIVO-1 trial, added positive statements about the TIVO-3 data and downplayed the negative OS results by calling it "not mature":

> In May 2016, we initiated enrollment in the TIVO-3 trial, a phase 3 trial of tivozanib in the third- and fourth-line treatment of patients with RCC. The TIVO-

> 3 clinical trial was designed to address the FDA's concern about the negative OS trend expressed in the complete response letter from June 2013. . . On November 5, 2018, we announced positive topline results from the primary analysis of the TIVO-3 trial. The trial met its primary endpoint for PFS, with a median PFS in the tivozanib arm of 5.6 months compared with 3.9 months in the sorafenib arm. Tivozanib demonstrated a 44% improvement in median PFS and 26% reduction in risk of progression or death compared to sorafenib (HR=0.74, p=0.02). Approximately 26% of patients received checkpoint inhibitor therapy in earlier lines of treatment, and PFS for tivozanib was longer than for sorafenib both in patients who received prior checkpoint inhibitor therapy and those who did not. ***The analysis of the secondary endpoint of OS was not mature at the time of the final PFS analysis, with only 46% of potential OS events having been reported. At the time of the preliminary OS analysis, no statistically significant difference in OS was observed (HR=1.06, p=0.69).*** The final OS analysis per protocol is planned for August 2019, two years following the date the last patient enrolled in the trial. In addition, we plan to present the totality of the data at medical meetings in 2019, and to the extent there is any meaningful change in OS at the time of such meetings, we would present those updated data.
>
> ***Based on the results of the TIVO-3 trial, together with the previously completed TIVO-1 trial, we plan to submit an NDA to the FDA within approximately six months from our announcement of topline data results of the TIVO-3 trial.***

(Emphasis added).

221. The Q3 2018 10-Q also contained merely generic, boiler plate representations concerning the risk that tivozanib and its clinical trials might prove unsuccessful, stating, in relevant part:

> The success of tivozanib will depend on several factors, including the following:
>
> - our ability to secure the substantial additional capital required to complete our clinical trials of tivozanib, including the TIVO-3 trial and the TiNivo trial;
> - successful design, enrollment and completion of clinical trials; [and]
> - a safety, tolerability and efficacy profile that is satisfactory to the FDA, EMA or any other comparable foreign regulatory authority for marketing approval[.]
>
> * * *
>
> Many of these factors are beyond our control, including clinical trial results, the regulatory approval process, potential threats to our intellectual property rights and the development, manufacturing, marketing and sales efforts of our collaborators. If we are unable to develop, receive marketing approval for and

> successfully commercialize tivozanib on our own or with our collaborators, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

222. Appended as exhibits to the Q3 2018 10-Q were signed certifications by Defendants Bailey and Dallas pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), certifying that "[t]he [Q3 2018 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934" and that "[t]he information contained in the [Q3 2018 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

223. AVEO and Defendants Bailey and Dallas either knew or recklessly disregarded that the statements referenced in ¶¶220-222 were materially misleading when made, *inter alia*, because (i) tivozanib had insufficient survival data to meet FDA approval following its initial 2013 rejection by the FDA; (ii) the survival data they presented to the public did not include all OS events; and (iii) this lack of sufficient survival data would put tivozanib at greater risk of delayed FDA approval.

224. A related November 9, 2018 press release stressed the "positive topline results" of TIVO-3 while again downplaying the negative OS data by calling it "immature" and saying it "showed no statistically significant difference." Again, the company stated how "well-tolerated" tivozanib was and how the results supported NDA submission: "Tivozanib was generally well-tolerated, with adverse events consistent with those observed in previous tivozanib trials, including the Phase 3 TIVO-1 trial in front-line RCC. . . Based on results from the TIVO-3 trial, together with the previously completed TIVO-1 trial of tivozanib in the first-line treatment of RCC, the Company plans to submit a potential New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in approximately six months."

225. Again, by calling the drug "well-tolerated," AVEO chose to downplay the serious adverse events that occurred on the drug.

226. AVEO either knew or recklessly disregarded that the statements referenced in ¶¶224-225 were materially misleading when made, *inter alia*, because (i) tivozanib had insufficient survival data to meet FDA approval following its initial 2013 rejection by the FDA; (ii) the survival data they presented to the public did not include all OS events; and (iii) this lack of sufficient survival data would put tivozanib at greater risk of delayed FDA approval.

227. On January 9, 2019, AVEO Oncology at the 37th Annual J.P. Morgan Healthcare Conference, Defendant Bailey acknowledged that tivozanib was "on the wrong side of the hazard ratio" but reiterated that the company planned to meet with the NDA soon and submit a NDA:

> Tivozanib has been through substantial clinical development over the years. We now have two Phase 3 studies where each of these studies we've met the primary end point. . . TIVO-3 is a third line, third and fourth actually, kidney cancer. This study was conceived in response to the complete response letter we received in 2013 from the FDA where they said: 'Do another study, power it for progression free survival and make it large enough to give us an assurance that there is not an adverse effect on overall survival.' So that's what we really set out to do with this study. At the end of last year, we were very pleased to announce we met the primary end point of progression free survival yet again. . . Moving on to the secondary endpoints, overall response rate, obviously the important measure of disease control and the ability to shrink the tumors, tivozanib again comes out on top . . . ***In the preliminary analysis we've done for overall survival, we're on the wrong side of the hazard ratio, we're above 1 when we presented this preliminary data. A couple of things to keep in mind. One is this is preliminary data—we've only seen about half of the potential events that will contribute to this final endpoint. In addition, we're collecting additional overall survival data and doing an analysis to try to understand why this would be the case that we're on the wrong side of the one hazard ratio.*** So we'll have an update on overall survival at the upcoming meeting of ASCU GU, which is February 16, and we're very excited about the opportunity to have an oral presentation to present this data. In addition, we'll continue to monitor the overall survival beyond that meeting and then up until August 2019, which is the protocol defined secondary end point or final analysis for overall survival. So stay tuned, it will be very interesting to see how that comes out.

> ***We have a pre-NDA meeting scheduled for the first quarter of this year where we'll start this dialogue. Then our goal is to submit the NDA in the first half of 2019 with a decision hopefully in 2020.***

228. AVEO and Defendant Bailey either knew or recklessly disregarded that the statements referenced in ¶227 were materially misleading when made, *inter alia*, because (i) tivozanib had insufficient survival data to meet FDA approval following its initial 2013 rejection by the FDA; (ii) the survival data they presented to the public did not include all OS events; and (iii) this lack of sufficient survival data would put tivozanib at greater risk of delayed FDA approval.

229. Throughout the Class Period, AVEO's officers and employees also made presentations at various other healthcare and investor conferences. The company filed related slide presentations with the SEC. Corporate slide presentations all played up TIVO-1's positive PFS figure and downplayed the OS results, stating they were confounded by crossover.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

230. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired AVEO securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

231. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, AVEO securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and

can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by AVEO or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

232. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

233. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

234. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of AVEO;
- whether the Individual Defendants caused AVEO to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of AVEO securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

235. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

236. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- AVEO securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold AVEO securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

237. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

238. Plaintiff may also rely, in part, on the presumption of reliance available for omissions under *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), in that the material misrepresentations alleged herein are primarily material omissions and not affirmative misrepresentations of fact.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

239. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

240. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

241. During the Class Period, Defendants knowingly or recklessly misrepresented material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. Specifically, among the other misrepresentations identified in detail in the paragraphs above, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the TIVO-3 trial was inadequately designed to address the OS concerns regarding AVEO's lead candidate drug, tivozanib, from the TIVO-1 trial presented back in the June 2013; (ii) tivozanib had insufficient survival data to meet FDA approval following its initial 2013 rejection by the FDA; and (iii) this lack of sufficient survival data would put tivozanib at greater risk of delayed FDA approval.

242. As specified above, each of the Individual Defendants either spoke directly on the topic of TIVO-3 or signed related public statements. TIVO-3 clearly involved a core operation of AVEO's business, as development of tivozanib was the stated focus of the company, and regulatory approval in the US was essential to the company's survival.

243. By virtue of their positions at AVEO, the Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to

ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

244. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of AVEO, the Individual Defendants had knowledge of the details of AVEO's internal affairs, especially with regard to this essential study.

245. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of AVEO. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to AVEO's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of AVEO securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning AVEO's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired AVEO securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

246. Even if Defendants did not have an absolute duty to disclose the true facts alleged herein as a result of the importance of those facts to AVEO's business and prospects, each of the Defendants assumed the duty to speak wholly and truthfully to investors regarding the topics on which he spoke.

247. During the Class Period, AVEO securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of AVEO securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of AVEO securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of AVEO securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

248. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

249. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against Defendant Bailey)

250. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

251. During the Class Period, Defendant Bailey controlled the operation and management of AVEO, and directed and oversaw AVEO's business and regulatory affairs and investor communications. Because of his position as AVEO's President, CEO and Director, and for the reasons alleged herein, Defendant Bailey knew the material adverse non-public information omitted from investors alleged above.

252. Defendant Bailey, as a result of his role as President, CEO and Director of AVEO, had the ability to and did exercise control over AVEO and its public representations to investors and analysts. He had the obligation to disseminate only truthful information with respect to AVEO's operations and the development and regulatory progress of its key drug, tivozanib, and to correct promptly any public statements issued by AVEO which had become materially false or misleading. Defendant Bailey, was a "controlling person" of AVEO within the meaning of Section 20(a) of the Exchange Act. In this capacity, he participated in AVEO's unlawful conduct which artificially inflated the market price of AVEO securities.

253. By reason of the above conduct, Defendant Bailey is additionally liable pursuant to Section 20(a) of the Exchange Act for the violations committed by AVEO.

254. Defendant Bailey, by virtue of the fact that the remaining Individual Defendants reported to him and were subordinate to him in the corporate structure of AVEO, also had the opportunity and power to control the public statements of the other Individual Defendants, and was a "controlling person" of them within the meaning of Section 20(a) of the Exchange Act. In this capacity, he participated in the remaining Individual Defendants.

255. By reason of the above conduct, Defendant Bailey is also liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Defendants Dallas, Ehrlich and Needle.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: July 24, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on July 24, 2019.

/s/ Daryl Andrews
Daryl Andrews